

## Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in October 2014.

### Original Approvals

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This section displays the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

#### ANADA Number: 200-522

Trade Name: Carprofen Sterile Injectable Solution  
Pioneer: Rimadyl®  
Ingredients: Carprofen  
Sponsor: Putney, Inc.  
Approval Date: October 15, 2014  
Status: Rx  
Route: Subcutaneous injection  
Species: Dogs  
Drug Form: Injectable solution  
Concentration: 50 mg/mL  
Indications: For the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs.

#### ANADA Number: 200-581

Trade Name: Flunazine®  
Pioneer: Banamine®  
Ingredients: Flunixin meglumine  
Sponsor: Cross Vetpharm Group Ltd.  
Approval Date: October 14, 2014  
Status: Rx  
Route: Oral  
Species: Horses  
Drug Form: Paste  
Concentration: 30 grams of paste contains flunixin meglumine equivalent to 1,500 mg of flunixin  
Indications: For the alleviation of inflammation and pain associated with musculoskeletal disorders in the horse.

### Supplemental Approvals

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This section displays the change(s) to the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

#### ANADA Number: 200-455

Trade Name: TYLOMED-WS  
Ingredients: Tylosin tartrate  
Sponsor: Cross Vetpharm Group Ltd.  
Approval Date: August 11, 2014

Supplemental approval of a change to veterinary prescription (Rx) marketing status to conform to reference (pioneer) product.

#### NADA Number: 141-244

Trade Name: Draxxin®  
Ingredients: Tulathromycin  
Sponsor: Zoetis Inc.  
Approval Date: October 16, 2014

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The following corrections or additions to the list were completed in October 2014.

This supplement provides for 1) the treatment of bovine respiratory disease associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis* in suckling calves, dairy calves, and veal calves; and 2) removal of the veal calf restriction (residue warning statements).

### NADA Number: 141-258

Trade Name: Zilmax®  
Ingredients: Zilpaterol hydrochloride  
Sponsor: Intervet, Inc.  
Approval Date: October 30, 2014

This supplement provides for: 1) component feeding of 60 mg zilpaterol hydrochloride/head/day for increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed, and 2) adding the following statement to the labeling for the use of zilpaterol hydrochloride in complete feed: "CAUTION: Not to be fed to cattle in excess of 90 mg/head/day in complete feed. If pen consumption of complete feed exceeds 26.5 lb/head/day (90 percent dry matter basis), zilpaterol should not be fed in complete feed."

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## Sponsor Change

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### ANADA Number: 200-033

Previous: Macleod Pharmaceuticals, Inc.  
New Sponsor: Neogen Corp.  
Drug Labeler Code: 059051

21 CFR 520.2613